

REMARKS

The Examiner has rejected claims 1-30 as follows:

Claims 1-17 and 20-30 were rejected under 35 USC 103(a) as being unpatentable over Rossling et al (WO97/19676 as translated in US 6294204). The Examiner further rejected claims 18-19 over Rossling and further in view of Setterstrom et al (US 6410056). The rejections are traversed.

Claims 1-17 and 20-30 recite a process for preparing microparticles where a hydrophilic active agent is added to a polymer solution in a vessel. A polymer solvent is selected based on its miscibility in the aqueous surfactant phase and the surfactant phase is selected such that the volume fraction of the surfactant phase will be at least 0.6 of the contents of the vessel. In this way, the drug loading of the microparticles may range up to 40%.

Rossling describes a similar process for the preparation of microparticles. However, there is nothing in Rossling to suggest the optimal solubility parameters of the polymer solvent and the aqueous surfactant phase. Further, Rossling does not suggest a high volume fraction of surfactant phase. Applicants disagree with the Examiner's assertion that selection of these parameters requires only routine skill. Rossling does not suggest the volume fraction of surfactant. Rossling's examples, and in fact the claims, describe fractions below 0.6. Further, Rossling describes a large variety of possible polymer solvents and surfactant phases and gives no guidance to the miscibility of the polymer solvent in the aqueous surfactant phase. Although similar processes, there is no suggestion in Rossling to carry out a process according to the current invention to produce microparticles with high drug loading and high encapsulation efficiency. In view of the above, Applicants believe that claim 1 as currently amended and its dependents are patentable over Rossling.

Claims 18 and 19 depend from claim 1. The Examiner has rejected these claims over Rossling in view of Setterstrom. Since the process of claim 1 is neither suggested nor described in Rossling and Setterstrom describes a very different process for the preparation of microspheres and further describes nothing about solubilities or surfactant phase volume fractions, claim 1 and further its dependents, claims 18 and 19 would not have been obvious over Rossling in view of Setterstrom.

Conclusion

In view of the amendments and remarks above, claims 1-30 are believed to be patentable in view of the references described and reconsideration and withdrawal of the 35 USC 103(a) rejections is respectfully requested. The Examiner is invited to contact the undersigned attorney at the number indicated below if it is believed that a telephonic interview would expedite prosecution of the present application.

Respectfully submitted,

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